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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,564	11/07/2000	Florian Kern	KREISLER1089	5234

7590 05/04/2004

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EXAMINER

SHANNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/600,564		KERN ET AL.	
	Examiner		Art Unit	
	Khatol S Shahnan-Shah		1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003 and 12 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment and response of 12/09/2003 and supplemental amendment of 12/12/2003 are acknowledged. The specification has been replaced by a substitute specification or replacement pages to correct minor spelling errors. Claims 14, 15, 19, 20 and 21 have been amended. Replacement drawings have been received.
2. Claims 14-26 are pending in this application. Claims 22-26 are withdrawn from consideration as being drawn to non elected inventions.
3. Claims 14-21 are under consideration.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 has been submitted with this office action.

Priority

6. Objection to the Priority statement made in paragraph 6 of the office action mailed 9/09/2003 is maintained. The applicants have not addressed this objection in their response.

Drawings

7. Applicants have submitted replacement drawings. However, this application, filed under former 37 CFR 1.60, lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be

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required to submit new formal drawings. In unusual circumstances, the formal drawings from the abandoned parent application may be transferred by the grant of a petition under 37 CFR 1.182.

Information Disclosure Statement

8. Objection to the Priority statement made in paragraph 8 of the office action mailed 9/09/2003 is maintained. The applicants have not addressed this objection in their response.

Objections Withdrawn

9. Objection to the specification made in paragraph 9 of the office action mailed 9/09/2003 is withdrawn in view of applicants amendments.

10. Objection to claims 14-21 made in paragraph 10 of the office action mailed 9/09/2003 is withdrawn in view of applicants amendments.

Rejections Withdrawn

11. Rejection of claims 14-21 under 35 USC § 112 first paragraph made in paragraph 12 of the office action mailed 9/09/2003 is withdrawn in view of applicants amendments.

12. Rejection of claims 14-21 under 35 USC § 112 second paragraph made in paragraph 14 of the office action mailed 9/09/2003 is withdrawn in view of applicants amendments.

Rejections Maintained

13. Rejection of claims 14-21 under 35 USC § 102(b) made in paragraph 17 of the office action mailed 9/09/2003 is maintained.

The rejection was as stated below:

Claims 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Woitas et al. (Journal of Immunology of Immunology, Vol. 159, No. 2, pp. 1012-1018, 1997).

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Claims are drawn to a method for identification of T-cell stimulating protein fragments comprising the following steps:

- detecting an amino acid sequence of an antigen;
- subdividing the amino acid sequence into fragments;
- synthesizing at least one protein fragment;
- incubating a suspension containing T-cells with the protein fragment;
- identifying an induced T-cell cytokine or activation of a marker by flow cytometry;
- assigning experimental runs in which T-cells have been stimulated and the stimulation has been recognized by a T-cell cytokine or an activation marker.

Woitak et al. teach a method for identification of T-cell stimulating protein fragments comprising the following steps:

- detecting an amino acid sequence of an antigen;
- subdividing the amino acid sequence into fragments;(see page 1013, column 1, paragraphs 8-9)
- synthesizing at least one protein fragment; (see page 1013)
- incubating a suspension containing T-cells with the protein fragment; (see page 1013, column 2, paragraph 2)
- identifying an induced T-cell cytokine or activation of a marker by flow cytometry; (see page 1013, column 2, paragraph 3)
- assigning experimental runs in which T-cells have been stimulated and the stimulation has been recognized by a T-cell cytokine or an activation marker.

(see page 1013 , column 2, paragraph 3).

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Woitas et al. describe the induction of CD30 and cytokines as a result of the HCV core protein or fragments thereof (see page 1013, column 1, paragraphs 8-9) acting on peripheral mononuclear cells of hepatitis patients (see abstract, pages 1013, 1014 and 1015). The peptides are incubated with cells (page 1013). The protein fragments essentially bound to MHC (page 1012). The T-cell cytokines such as, for example IL-2 and $\text{INF}\gamma$ (see page 1014) undergo flow cytometry and therefore are identified as individual cell level (see page 1013 and 1014). The T-cell stimulation of both the protein fragments used are 25 amino acids long, and the control peptide is evaluated, i.e. protein fragments are allocated to T-cell stimulation (see figures 2 and 3 in page 1016 and page 1017). Woitas et al. teach both long and short incubation times. Woitas et al. teach long incubation time up to 40 hours (see page 13, column 2, paragraph 2) and short incubation time such as 30 minutes (see page 13, column 2, paragraph 3). The prior art anticipates the claimed invention.

Applicants' arguments filed 12/09/03 have been fully considered but they are not persuasive.

Applicants argue " Paragraph (f) in claim 14 functionally delineates a window of time during which the incubation of T-cells with peptides is performed. This window of time is sufficient for the peptides to be taken up by the T-cells, but too short for there to be appreciable cell proliferation". Applicants further argue " Woitas' method leaves peptides and cells together for 40 hours". Applicants further argue, " that Woitas does not contain an enabling disclosure".

It is the examiner's position that Woitas et al. describe the induction of CD30 and cytokines as a result of the HCV core protein or fragments thereof (see page 1013, column 1, paragraphs 8-9) acting on peripheral mononuclear cells of hepatitis patients (see abstract, pages

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1013, 1014 and 1015). The peptides are incubated with cells (page 1013). The protein fragments essentially bound to MHC (page 1012). The T-cell cytokines such as, for example IL-2 and INF γ (see page 1014) undergo flow cytometry and therefore are identified as individual cell level (see page 1013 and 1014). The T-cell stimulation of both the protein fragments used are 25 amino acids long, and the control peptide is evaluated, i.e. protein fragments are allocated to T-cell stimulation (see figures 2 and 3 in page 1016 and page 1017). Woitas et al. teach both long and short incubation times. Woitas et al. teach long incubation time up to 40 hours (see page 13, column 2, paragraph 2) and short incubation time such as 30 minutes (see page 13, column 2, paragraph 3). The claimed invention step (f) claim 14 recites the function limitations or phrases “sufficiently long”, “sufficiently taken up” and “sufficiently short” which do not define a specific time limit for the incubation of the cells. The specification does not define or set metes and bounds of these periods therefore in absence of evidence to the contrary Woitas et al. teaches both long and short incubation periods and anticipates the claimed invention.

New Objections and Informalities

14. Note: Amendments to the claims submitted 12/09/2003 recite status of claims 19 and 20 as “previously presented” it should have recited “ currently amended” because those claims have been amended in the amendments to the claims submitted 12/09/2003 by the applicants.

15. Amended claim 14 step (e) (page 2 of the amendments 1st line) recites “ cytokinecytokinees”. It is not clear what applicants intend in said recitation?

Conclusion

16. No claims are allowed.

17. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair->

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Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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April 27, 2004



RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER